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09/668,508	09/22/2000	Henry E. Young	1304-1-019CIP	1973

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EXAMINER

TON, THAIAN N

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 04/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/668,508

Applicant(s)

YOUNG ET AL.

Examiner

Thaian N. Ton

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 14-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

### DETAILED ACTION

Applicants' Amendment and Response, filed 1/21/05, has been entered. Claims 14 and 15 have been amended. Claims 14-17 are pending and under current examination.

#### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection. 37 CFR 1.118 (a) states that "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application".

The claims, as currently amended recite that the differentiation of the pluripotent embryonic-like stem cell give rise to each and any of endodermal, ectodermal and mesodermal lineages, and do not give rise to functional gametes. This is considered new matter because there is no description in the specification for a pluripotent embryonic-like stem cell that does not give rise to functional gametes.

The specification teaches that totipotent embryonic stem cells give rise to functional gametes. See p. 3, lines 30-31. However, there is no support in the specification for an embryonic-like, pluripotent cell that does not give rise to functional gametes.

To the extent that the claimed compositions and/or methods are not described in the instant disclosure, claims 14-17 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, since a disclosure cannot teach one to make or use something that has not been described.

MPEP §2163.06 notes:

*If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. In re Rasmussen, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981).*

MPEP §2163.02 teaches that:

*Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application.*

MPEP §2163.06 further notes:

*When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved.*

*Applicant should therefore specifically point out the support for any amendments made to the disclosure. (Emphasis added).*

Applicants' Response fails to provide specific guidance as to where support for this claim language can be found in the instant specification, as the response states that the support, "[C]an be found generally through Applicants' specification." See p. 4 of the Response. If Applicants feel that the instant specification provides sufficient description for the amendment to the claims, they are invited to point specifically to page and line number for where this support may be found.

***Claim Rejections - 35 USC § 112***

The prior rejection of claim 14, and its dependent claims, is withdrawn in view of Applicants' amendments to the claim, which now recites the term "isolated".

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims, as instantly amended, recite that the cells are capable of differentiation to cells of each and any of endodermal, ectodermal and mesodermal lineages (see claim 14, line 3 and claim 15, part (a)). The metes and bounds of the

Art Unit: 1632

term each and any is unclear because it encompasses each lineage in the singular, or any of the lineages, and any combinations that can be made from these lineages. One could not ascertain the metes and bounds of this term, and thus, the claims are found to be indefinite.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 14-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Capecchi *et al.* [**Scientific American**, 270(3):34-41 (1994)]. This rejection is maintained for reasons of record.

Applicants argue that Capecchi teaches ES cells, which are totipotent, and point to the instant specification for support, wherein it is taught the ES cells, when injected into embryos can give rise to all somatic lineages, as well as functional gametes. Applicants argue that the instant invention is directed to pluripotent cells that are capable of differentiation to all somatic lineages, but do not give rise to functional gametes. Applicants argue that this distinction is now in the claims as amended and thus, Capecchi do not teach the claimed invention. See p. 5 of the Response.

This is not found to be persuasive. Not all totipotent cells give rise to functional gametes. This is underscored by the fact Capecchi teaches that embryos that contain ES cells generate chimeric mice (see p. 38, How Targeted Gene Replacement is Accomplished in Mice). Chimeric mice, by definition, contain cells from two different strains of mice. These chimeric mice must then be mated and screened for evidence of germ line transmission. Thus, although ES cells can give rise to functional gametes, it is equally possible that they do not, as evidenced by the requirement for back-crossing and testing the resulting mice for germ line transmission.

Capecchi teach the inactivation of target genes by homologous recombination, and the insertion of a *neo* resistance gene, which serves as a positive selection marker in mouse ES cells. See Figure, p. 36. They teach that the ES cells are then cultured and grown into surrogate mothers to generate chimeric mice. See p. 38, Figure. Note that the claimed cells are not distinguished from those taught by Capecchi. Capecchi fulfills the limitations of the claims (the differentiation to cells of any endodermal, ectodermal, mesodermal lineage) by showing the generation of mice; further, the methods of producing the genetically engineered cells are also anticipated by Capecchi because they teach transfection of pluripotent embryonic-like stem cells. Accordingly, Capecchi anticipate the claims.

Claims 14-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Povey *et al.* [**Blood**, 92(11):4080-4089 (1998)]. This rejection is maintained for reasons of record.

Applicants argue that Povey do not teach the claimed invention because hematopoietic stem cells (HSCs) are only capable to differentiation to hematopoietic cells, which are one type of mesodermal cells. Thus, these cells cannot anticipate the claimed invention because they do not differentiate to each and any of the three germ layer lineages. Applicants argue that their cells are not limited to one or two of the lineages, but can differentiate to any cells of each and all three germ layer lineages. See pp. 5-6 of the Response.

Applicants' arguments have been considered but are not persuasive. The claims, as instantly amended, require the differentiation to each and any of the three germ layer lineages. This claim language encompasses differentiation of cells to each of the three lineages, or combinations of these lineages (for example, 1, 2 or 3 in any combination). The amendment does not overcome the art because Povey teaches transfection of HSCs, which are capable of differentiation to at least one of the lineages (mesodermal) required by the claims.

Povey teach the transfection of pluripotent human hematopoietic stem cells using a retroviral vector. They teach that hematopoietic stem cells are capable of multilineage differentiation and self-renewal (see *Abstract*). Particularly, they teach that the cells were transduced using a viral producing cell line that expresses



the membrane-bound form of human stem cell factor (see *Abstract* and *Methods and Materials*). Further, as the instant claims fail to be distinguished from the cells taught by the art, Povey anticipates the claims.

Claims 14-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Verma *et al.* [*Gene Therapy*, 5:692-699 (1998)]. This rejection is maintained for reasons of record.

Applicants argue, similarly as above for Povey *et al.*, that Verma do not teach the claimed invention because they only teach transfection of HSCs, which are not capable of differentiation to the three germ layer lineages. Thus, Applicants argue that Verma do not anticipate the claim. See p. 6, 1<sup>st</sup> full ¶ of the Response.

This is not persuasive for the reasons stated previously. Briefly, the amendment to the claims encompasses differentiation of cells to each of the three lineages, or combinations of these lineages (for example, 1, 2 or 3 in any combination). The amendment does not overcome the art because Verma teaches transfection of HSCs, which are capable of differentiation to at least one of the lineages (mesodermal) required by the claims.

Verma teach the transfection of hematopoietic progenitor cells using a CMV-CAT reporter plasmid. See *Abstract*. They teach that the hematopoietic progenitor cells are isolated from bone marrow, peripheral and umbilical cord blood and are able to differentiate into cells of the hematopoietic lineage. See p. 692, 1<sup>st</sup> column.

Further, as the instant claims fail to be distinguished from the cells taught by the art, Verma anticipates the claims.

Claims 14-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Piedrahita *et al.* [**Biol. Of Reprod.**, 58:1321-1329 (1998)].

Piedrahita teach the generation of transgenic porcine chimeras using primordial germ cells (PGCs)-derived colonies. In particular, they teach the isolation of the PGCs from 25-27 day old pig fetuses, (p. 1321, 2<sup>nd</sup> column, Methods & Materials), they show the ability of the PGC to survive and proliferate in an undifferentiated state (see p. 1322, 1<sup>st</sup> column, AP Staining), the ability of the PGCs to differentiate into embryoid bodies (p. 1322, 1<sup>st</sup> column), the transformation of PGCs by electroporation using a plasmid that contained humanized GFP (p. 1322, col. 1-2) and the generation of chimeric pig fetuses and pigs using the transformed PGCs.

Piedrahita anticipate the claimed invention because the PGCs they teach are capable of differentiation into the three germ layers (as evidenced by both the generation of embryoid bodies and the generation of chimeric pig fetuses and chimeric piglets). Chimeric animals, by definition, have some cells have cells that are contributed by the donor cells, and some from the cells of the recipient blastocysts. Piedrahita teach the analysis of transgene expression and show that

Art Unit: 1632

the pigs expressed the transgene in different tissues, they teach that analysis of the developing fetuses suggests that although some may have germ line transmission, it would require that the chimeric cells contribute to the germ line. See p. 1328, 2<sup>nd</sup> column, 2<sup>nd</sup> full ¶, and p. 1329, 1<sup>st</sup> column, 2<sup>nd</sup> ¶. Accordingly, Piedrahita anticipate the claimed invention.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The prior rejection of claims 14-17 under 35 U.S.C. 103(a) as being unpatentable over Pittenger *et al.* in view of Sambrook *et al.* is *maintained* for reasons of record.

Applicants argue that the cells, as instantly claimed, are not obvious over Pittenger in view of Sambrook, because the mesenchymal cells taught by Pittenger are only capable of differentiating into cells of mesenchymal lineage. Applicants argue that the claims, as now amended, distinguish the claimed cells from the art, because they require the differentiation of the cells into each and any of the germ layer lineages. Applicants argue that this limitation is not in the alternative, and thus is not made obvious or anticipated by stem cells that are capable of only differentiating into a single or even two lineage types. Applicants point specifically to the specification for this support, and thus conclude that Pittenger's mesenchymal cells are not those of the instant invention because they only have the capacity to differentiate into mesenchymal lineage cells. See pp. 6-7 of the Response.

Applicants' arguments have been considered, but are not persuasive. As stated previously, the amendment to the claims fails to distinguish the cells from those, as taught by the combination of Pittenger and Sambrook. The amendment to the claims encompasses differentiation of cells to each of the three lineages, or combinations of these lineages (for example, 1, 2 or 3 in any combination). Accordingly, Pittenger's cells teach those of the claimed invention because the cells

are capable of differentiation into mesenchymal lineage cells, and thus, fulfill the limitation of the claims. In response, it is noted that the claims are not written in the alternative, because they recite "each and any", which can mean each of the lineages, or any of the lineages

Pittenger teach human mesenchymal stem cells isolated from adult bone marrow which are found to differentiate into multiple mesenchymal lineages *in vitro* [see p. 143, 2<sup>nd</sup> column, 1<sup>st</sup> full paragraph]. Pittenger teach that these mesenchymal cells were characterized by their ability to proliferate in culture [see Figure 1]. Pittenger teach that the differentiation potential of the mesenchymal stem cells was tested by specific differentiation in adipogenic differentiation, chondrogenic differentiation and osteogenic differentiation under specific conditions [see pp. 144-145]. They differ from the claimed invention in that they do not teach transfecting the pluripotent embryonic stem-like stem cells with a DNA construct comprising at least one of a marker gene or a gene of interest.

However, prior to the time of the claimed invention, Sambrook teach methods of transfecting mammalian cells with any gene of interest [see 16.33-16.38]. Accordingly, in view of the combined teachings of Pittenger and Sambrook, it would have been obvious for one of ordinary skill in the art at the time the claimed invention was made, to use the mesenchymal stem cells, as taught by Pittenger and transfect them with any DNA of interest, with a reasonable expectation of success. One of skill in the art would have been sufficiently motivated to make such a

modification, as expression of proteins in mammalian cells can provide different purposes, as described by Sambrook on p. 16.3, such as for the expression of large amounts of protein of biological interest, or to study the biosynthesis and intracellular transport of proteins following their expression in various cell types.

Thus the claimed invention as a whole was clearly *prima facie* obvious at the time the claimed invention was made especially in the absence of sufficient, clear and convincing evidence to the contrary.

Claims 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shamblott when taken with Sambrook *et al.* This rejection is maintained for reasons of record.

Applicants argue that the cells taught by the instant invention are distinct from embryonic stem cells, and primordial germ cells, particularly in that they are pluripotent and are not totipotent, and do not give rise to functional gametes. See p. 7 of the Response.

This is not found to be persuasive. As stated above and previously, the instantly claimed cells are not found to be distinguished by that of the art because there are no requisite characteristics that differentiate them from, for example, the PGCs taught by Shamblott. Shamblott teaches that the PGCs are pluripotent, as are the claimed cells. The specification teaches that a pluripotent stem cell is capable of self-regeneration, differentiation to cells of endodermal, ectodermal and

mesodermal lineages (see p. 35-36) and further, that by Applicants' own definition, that pluripotent cells do not give rise to functional gametes, therefore it would be inherent, by Applicants definition of pluripotent cells, that because Shamblott teaches pluripotent cells, they would not give rise to functional gametes.

Shamblott *et al.* teach the generation of human pluripotent stem cells from gonadal ridges and mesenteries containing primordial germ cells [PGCs] and teach that embryoid bodies collected from these cultures revealed a wide variety of differentiated cell types, including derivatives of all three embryonic germ layers [see *Abstract*]. In particular, Shamblott *et al.* teach that gonadal ridges and mesenteries of 5 to 9 week old human fetuses and cells initially cultured on a layer of mouse STO fibroblast feeder layer. The cells formed embryoid bodies, which were collected and analyzed immunohistochemically [see pp. 13726-13727, *Materials & Methods*]. It was found that the embryoid bodies demonstrated derivatives of the three embryonic germ layers [see p. 13729, 2<sup>nd</sup> column and Table 1]. Note that Shamblott teach the pluripotent embryonic-like stem cells because the claims do not provide any requisite characteristics (*e.g.*, specific markers, etc.) of the claimed embryonic-like stem cells such that they would be distinguished from the cells taught by Shamblott. The claims recite that the embryonic-like stem cells are "derived from non-embryonic or postnatal animal cells or tissue;" however, this recitation does not differentiate them from the cells as taught by Shamblott. Further, the method claim has been included in this rejection because the cells as

instantly claimed are not distinguishable from those taught in the art. The cells as taught by Shamblott fulfill the requirements of the claims because they are capable of differentiation to cells of each and any of endodermal, ectodermal and mesodermal lineages, and are capable of self-renewal.

Shamblott do not teach the transfection of the pluripotent stem cells to produce a genetically engineered pluripotent stem cell. However, prior to the time of the claimed invention, Sambrook teach methods of transfecting mammalian cells with any gene of interest [see 16.33-16.38]. Accordingly, in view of the combined teachings of Shamblott and Sambrook, it would have been obvious for one of ordinary skill in the art at the time the claimed invention was made, to use the PGCs, as taught by Shamblott and transfect them with any DNA of interest, with a reasonable expectation of success. One of skill in the art would have been sufficiently motivated to make such a modification, as expression of proteins in mammalian cells can provide different purposes, as described by Sambrook on p. 16.3, such as for the expression of large amounts of protein of biological interest, or to study the biosynthesis and intracellular transport of proteins following their expression in various cell types.

Thus, the claimed invention, as a whole, is clearly *prima facie* obvious in the absence of evidence to the contrary.



Claims 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thomson when taken with Sambrook *et al.* This rejection is maintained for reasons of record.

Applicants argue, as previously, that Thomson's cells are distinct and unobvious from the instantly claimed cells because Thomson's cells are totipotent cells, and the cells of the instant invention are pluripotent and do not give rise to functional gametes. See p. 7-8 of the Response.

This is not found to be persuasive. As stated above and previously, the instantly claimed cells are not found to be distinguished by that of the art because there are no requisite characteristics that differentiate them from, for example, the pluripotent cells, as taught by Thomson. Thomson teaches that the isolated cells are pluripotent, as are the claimed cells. The specification teaches that a pluripotent stem cell is capable of self-regeneration; differentiation to cells of endodermal, ectodermal and mesodermal lineages (see p. 35-36) and further, that by Applicants' own definition, that pluripotent cells do not give rise to functional gametes, therefore it would be inherent, by Applicants definition of pluripotent cells, that because Shamblott teaches pluripotent cells, they would not give rise to functional gametes.

Thomson teach the isolation of ES cells from the rhesus monkey. See p. 7844, *Materials and Methods*, col. 2. The cells are capable of maintaining an undifferentiated state and proliferate indefinitely, and have the potential to

Art Unit: 1632

differentiate into derivatives of all three embryonic germ layers. They teach that the cells differentiated into cells of endoderm, mesoderm and ectoderm. See *Abstract* and p. 7846, col. 1-2, bridging ¶. Note that the claims fail to distinguish the claimed cells from the cells taught by Thomson. Thus, the method claim has been included in the rejection because the cells used in the method are not distinguished from those taught by Thomson. Thomson do not teach that the ES cells are genetically engineered to express a gene or protein of interest.

However, prior to the time of the claimed invention, Sambrook teach methods of transfecting mammalian cells with any gene of interest [see 16.33-16.38]. Accordingly, in view of the combined teachings of Thomson and Sambrook, it would have been obvious for one of ordinary skill in the art at the time the claimed invention was made, to use the pluripotent embryonic stem cells, as taught by Thomson and transfect them with any DNA of interest, with a reasonable expectation of success. One of skill in the art would have been sufficiently motivated to make such a modification, as expression of proteins in mammalian cells can provide different purposes, as described by Sambrook on p. 16.3, such as for the expression of large amounts of protein of biological interest, or to study the biosynthesis and intracellular transport of proteins following their expression in various cell types.

Thus, the claimed invention, as a whole, is clearly *prima facie* obvious in the absence of evidence to the contrary.

Art Unit: 1632

***Conclusion***

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Thaian N. Ton whose telephone number is (571) 272-0736. The Examiner can normally be reached on Monday through Friday from 8:00 to 5:00 (Eastern Standard Time), with alternating Fridays off. Should the Examiner be unavailable, inquiries should be directed to Ram Shukla, SPE of Art Unit 1632, at (571) 272-0735. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the Official Fax at (571) 273-8300. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*tnt*

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